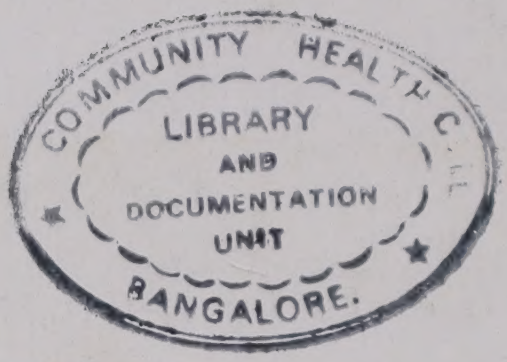
Herbal Remedies: Consumer Protection Concerns

Dr K Balasubramaniam

Consumers International

Regional Office for Asia and the Pacific



Erratum

Page 20 para 6 should read as follows:

"The annual market for traditional medicines is approximately US$800 million.(66) This is more than double that of the market for modern pharmaceuticals which is about US$350 million.(67)

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Dr K Balasubramaniam

Dr Kumariah Balasubramaniam graduated in medicine from the University of Sri Lanka. He completed his PhD in Clinical Pharmacology in 1970 at the University of Manchester, United Kingdom. He held the post of Professor and Head, Department of Pharmacology at the University of Sri Lanka until 1978.

For the period 1978-1983, Dr Balasubramaniam was the Senior Pharmaceutical Adviser in the Technology Division, of the United Nations Conference on Trade and Development (UNCTAD) in Geneva.

In 1983 he was transferred to the Caribbean Community Secretariat (CARICOM) in Guyana where he was the Pharmaceutical Adviser for three years. While in CARICOM Dr Balasubramaniam worked with Ministries of Health in the 13 Member States in formulating and implementing a Caribbean Regional Pharmaceutical Policy. In 1987 Dr Balasubramaniam joined Consumers International, Regional Office for Asia and the Pacific in Penang as the Pharmaceutical Adviser.

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Summary, Conclusions and Recommendations

"Maintains Healthy Cholesterol: Reduces Total Cholesterol, Reduces LDL 'Bad' Cholesterol, Reduces Triglycerides and Increases HDL 'Good' Cholesterol."

"Suitable for migraine, weak heart, hernia, menstrual pain, kidney stones, rheumatism, sexual stress, impotence, frost-bite, internal and external cancer and infection."

The first claim appears on the label of Cholestin, a recently launched cholesterol lowering natural 'dietary supplement' in the US. The second is an advertisement for 'Tea of Longevity', a herbal tea, which appeared in a daily newspaper in Malaysia in 1995. A 150 mg pack of this herbal tea costs between 160-240 Malaysian Ringgits. This is equivalent to about 10 days wages of an unskilled worker in Malaysia.

These health claims have not been approved by the drug regulatory agencies in either country. They are addressed directly to the consumer and reflect the major concerns consumers have on the way herbal remedies are marketed. The extent of consumer concern is also evident from the fact that since 1990 the US Congress has received more mail on the regulation of herbal remedies than any other issues including Bosnia, the Gulf War, Somalia, gun control, tax reform and health care reform!

This paper describes the legal control, patterns of utilisation, and consumers perceptions of herbal remedies in selected countries. Based on the analysis of the empirical data obtained, some recommendations for assuring the safety, efficacy and quality of herbal remedies are suggested.

There is now documented evidence that people in both developed and developing countries are purchasing and consuming herbal remedies in increasing amounts. There is also evidence that some of the herbal remedies in the market are not safe, effective and of good quality.

To examine, study and analyse the utilisation of herbal remedies in developed and developing countries, it will be useful to classify herbal remedies into the following three categories:

i. Phytomedicines sold as over-the-counter (OTC) products in modern dosage forms;
ii. Dietary supplements, containing herbal products, in modern dosage forms;
iii. Traditional medicine, consisting of either crude, semi-processed or processed medicinal plants and herbs.

Phytomedicines and dietary supplements are used by consumers in developed countries and those in the urban areas of developing countries.

Traditional medicine, according to the World Health Organization (WHO) is believed to serve the health needs of about 80 per cent of the world's population. It is relevant to note that in the US because of the difficulty of approving herbs as OTC drugs and the limitations placed on health claims for dietary supplements, particularly for herbs, there is a suggestion to create a third category - traditional medicines.

In both developed and developing countries, there are no comprehensive integrated national policies on herbal remedies which will facilitate drug regulators and health administrators to regulate the market and ensure that all herbal remedies in the market are safe, effective, of good quality, of reasonable cost and are used rationally. A major recommendation follows from this conclusion - the need to recommend guidelines for developing national policies on herbal remedies. These guidelines can serve as a model to enable individual countries to develop their own national policies on traditional medicines and herbal remedies including appropriate legislation to provide legal support for the national policy to regulate the market.

The proposed guidelines should take into consideration the various consumer protection concerns identified in this paper so that appropriate components can be formulated to take care of these concerns.

1. A model legislation on traditional medicines needs to be developed. At present there seems to be as many approaches to regulating herbal remedies as there are countries. Some countries such as Australia and Germany have useful components in their legislations which may be incorporated into the proposed recommendations. The Japan Chinese -Medicine Manufacturers have developed voluntarily "Regulations for Manufacturing Control & Quality Control of Ethical Extract Products in Kampomedicine (Oriental Medicine) Formulations", a useful model for developing Good Manufacturing Practices (GMP) for traditional medicines.

2. It will be useful to have universally acceptable definitions for the various terms used such as herbs, botanicals, medicinal plants, herbal remedies, phytomedicines, dietary supplements, traditional medicines. In this context it is relevant to note the definition of a 'therapeutic good' in the Australian law which states "Any product that is likely to be thought to be a therapeutic good for any reason, most often because of advertising, dosage form or appearance."

3. Consumers are confused over tens of thousands of herbal remedies in the market. It will not be possible to formulate a national policy to regulate these tens of thousands of herbal remedies. Consumers want this symposium to debate the concept of a limited number of useful herbal remedies and traditional medicines. This could be at two levels:
   - Limited number of useful medicinal plants and herbs for use at the household level.
   - Limited number of phytomedicines and traditional medicines and
   - Development of a formulary of phytomedicines.

4. Herbs, which are in fact drugs, are regulated and sold as foods in several countries. Consumers are concerned that herbal products regulated as dietary supplements will not provide an adequate level of safety. Consumers ask for a pre-market safety review for plant derived products marketed as food supplements and compulsory post-marketing surveillance.

5. At present FDA can intervene only if there is evidence of injury to consumers by dietary supplements. Consumers demand legislation that can proactively regulate for safety but will never accept a legislation that provides for reactive safety regulation after evidence of injury has been proved.

6. There is no monitoring and control over advertising and promotion of herbal remedies in almost all countries. In some countries the regulation applies to media advertising and health claims on packages but no control over the promotional practices of medical representatives when they visit health professionals. Consumers ask for the development of an Ethical Criteria for Promotion of Herbal Remedies. This should also include promotional practices of medical detailmen and direct selling of health products to consumers.

7. Modern pharmacies stock herbal remedies and pharmacists are expected to make appropriate product selection to consumers. But at present there are no authoritative sources from where pharmacists can obtain relevant information on herbal remedies to advise consumers and other health professionals. Consumers request this symposium to examine how best to provide this information to pharmacists.

8. There is uncontrolled cross-practice. This means that practitioners not trained in a particular system prescribe and dispense drugs belonging to that system indiscriminately. This should be prevented by appropriate legislation.

9. Consumers propose that there should be self-regulation by appropriate professional bodies as well as state legislative control on the training, certification and registration of traditional healers and practitioners.

10. There is insufficient data on the per capita consumption of traditional medicines in developing countries. Estimates are available for Malaysia and the Republic of Korea. In Malaysia the per capita consumption of traditional medicines is more than double that of modern pharmaceuticals although traditional healers are not recognised in Malaysia and there is no formal system of traditional health care. In the Republic of Korea, the per capita consumption of traditional medicines is about 36 per cent more than that of modern drugs.

    Consumers consider that it will be important to carry out a cost/benefit analysis of herbal remedies and traditional medicine in a selected number of countries and make it available to consumers and health administrators.

11. Consumers in both developed and developing countries use both modern and traditional medicines simultaneously. But they do not provide this information to the prescriber or dispenser. There is a potential risk of adverse drug interactions. Increasing public awareness of the benefits and risks associated with the use of traditional medicines should be built into the components of a national policy on traditional medicines and herbal remedies.

12. There should be a structure and mechanism in place for an international alert system for rapid sharing of information on toxicity and adverse reactions to herbal products among drug regulators.

13. The paper concludes with an appeal for a new approach to the evaluation of traditional medicines.

Consumers International Regional Office for Asia and the Pacific will be pleased to collaborate with UNIDO in following up on the recommendations that will be adopted by this international symposium.

1. Introduction

There are more effective, safe and good quality modern pharmaceuticals available today than ever before. However, it is paradoxical that consumers, particularly in the developed countries, are purchasing and using more and more herbal remedies.

There is now ample documented evidence that people in both developed and developing countries are purchasing and consuming herbal remedies and traditional medicines in increasing amounts. **There is also evidence that some of the herbal remedies in the market are not safe, effective and of good quality. This raises the issue of consumer safety.**

Consumers International (CI), a global federation of 214 organisations from 92 countries, representing consumers worldwide has consumer safety high on its agenda. CI is pleased to participate in this symposium, which will, among other issues examine consumer protection concerns.

What herbal remedies are the people in advanced industrialised countries such as the US and Western Europe and those in poor developing countries in sub-Saharan Africa and South Asia, consuming? The morbidity patterns are different and so is the pattern of utilisation of modern pharmaceuticals between developed and developing countries. What then is, the pattern of utilisation of herbal remedies and what are the consumer concerns in these countries?

To answer these questions and understand the issues it will be useful to classify herbal remedies into the following three categories:

1. *Phytomedicines* or *Phytopharmaceuticals* sold as over-the-counter (OTC) products in modern dosage forms such as capsules, tablets and liquids for oral use.

2. *Dietary supplements* containing herbal products, also called nutraceuticals, available in modern dosage forms.

These two types of herbal remedies are used by consumers in developed countries and those in urban areas of developing countries. These herbal remedies are gradually occupying increasing shelve space in modern pharmacies.

3. *Herbal remedies* consisting of either crude, semi-processed or processed medicinal plants and herbs. These remedies are available at two levels:

   i) Traditional beliefs, norms and practices based on centuries old experiences of trials and errors, successes and failures at the household level. These are passed through oral tradition and may be called, "people's health culture", home remedies or folk remedies. These have a vital place in primary health care in developing countries. A very good example was the universal availability of home made, cereal based oral rehydrating fluids in all cultures in developing countries till they were displaced by the commercial varieties of

oral rehydrating solutions which have been skillfully and aggressively marketed by the drug industry.

ii) A codified system of traditional medicine at the level of the traditional healer.

In the context of developing countries, consumer protection concerns cannot be realistically studied by examining herbal remedies in isolation. They should be taken together with traditional medicine. Traditional medicine includes the indigenous knowledge available in the community, the traditional healers and the means by which they provide health care, namely herbal remedies. Consumer protection and safety are closely related to herbal remedies, the prescribing practices of traditional healers and the health care systems in which they operate.

Having stated that the prescribing practices of traditional healers are also cause for consumer concern, it is also understood that this symposium cannot examine issues related to the training, certification and registration of traditional healers. However it will be necessary to reflect these concerns in the conclusions of the symposium. This will inform policy makers in developing countries to examine and develop appropriate policy measures to train, certify and register traditional healers and to regulate and control their professional practice.

In this paper the terms "traditional medicine" and 'herbal remedies' will be used interchangeably to describe the third group of herbal remedies used in developing countries.

It is also the term used by the World Health Organization (WHO), health administrators and policy makers in all developing countries. According to WHO, traditional medicine is believed to serve the health care needs of about 80 per cent of the world's population. The goal of Health for All by the Year 2000 cannot be achieved without traditional medicine. (1, 2, 3, 4, 5)

While there is a distinct difference between the patterns of utilisation of traditional medicine/herbal remedies in the developed and developing countries, consumer concerns are the same the world over. These include:

- Safety;
- Efficacy;
- Quality;
- Costs
- Unethical promotion; and
- Irrational use

of traditional medicine and herbal remedies.

Inspite of the fact that consumer concerns are the same in both developed and developing countries, international conferences that have been convened to study traditional medicines, herbal remedies and consumer protection concerns fall into two distinct categories.

For example, the July 1996 Open Conference on Botanicals for Medical and Dietary Uses: Standards and Information Issues, convened in Washington DC, July 7-9, 1996 looked exclusively at problems and prospects facing consumers in developed countries.

On the other hand, all international, regional and national conferences organised by the WHO and its Traditional Medicines Programme were confined mainly to the use of traditional medicine in developing countries. (1,2,3,4,5)

Consumers believe that sharing of information on consumer protection measures between developed and developing countries would be advantageous to both for the following reasons:

i) Developed countries have effective and efficient regulatory control over modern pharmaceuticals. These may serve as useful models to enact appropriate legislation to regulate herbal remedies;

ii) Developing countries have had several centuries of experience with the use of traditional medicine in health care. Developed countries may find this experience useful;

iii) Neither developed nor developing countries have an effective regulatory mechanism to ensure the safety, efficacy and quality of herbal remedies;

iv) Almost all herbal remedies marketed in developed and developing countries are OTC products, although some of these are known to be toxic;

v) In both developed and developing countries a herbal medicine, if marketed as food, is not regulated; but if the same product is marketed as a traditional medicine, it is regulated;

vi) In all developed and most developing countries, there are no systems, self-regulatory or otherwise, for the training, certification and registration of traditional healers or herbalists. Consumers have no guarantee that the traditional healers or the herbalists whom they visit to obtain health care have the necessary qualifications.

CI is pleased that this International Symposium will among other things examine consumer protection, and the use and abuse of herbal remedies in both developed and developing countries.

One of the objectives of this symposium will be to strengthen consumer protection and consumer safety in a well regulated market where safe and effective herbal remedies of good quality are available at affordable prices and are used rationally.

To achieve this objective, this symposium will have to recommend guidelines for developing national policies on herbal remedies which can serve as a model to enable countries to develop their own national policies on traditional medicine and

herbal remedies including appropriate legislation to provide legal support for the national policy to regulate the market.

Policy recommendations have to be based on a critical analysis of empirical data on traditional medicine and herbal remedies in developed and developing countries. This data will include:

i) Patterns of utilisation and consumers' perceptions of traditional medicines and herbal remedies;

ii) Existing legislation to control and regulate the herbal remedies market;

iii) Problems faced by countries in regulating the market;

iv) The marketing and promotional practices of the herbal drug industry;

v) The training, certification and registration of traditional healers and herbalists; and

vi) The role that traditional medicines and herbal remedies play in the overall health care services of a country in providing health care to its people.

This paper attempts to review the available data by describing the experiences of selected countries. And based on analysis of the data it suggests appropriate recommendations.

2. Regulation, patterns of utilisation and consumers' perceptions of herbal remedies and traditional medicines in selected countries

In the developed countries, consumers are making a deliberate choice in opting for herbal remedies. Their popularity is widespread in North America, Western Europe, Japan and Australia.

In the developing countries, on the other hand, a vast majority of the people use traditional medicines because modern health care services are not accessible, available or affordable to them.(1,2,3,4,5)

The worldwide market for phytomedicines was US$12.4 billion in 1994. (Table 1)

Table 1: Worldwide phytomedicine market, 1994.

Worldwide Phytomedicine Market, 1994 per Dr Grunwald, PhytoPharm, Phytotherapeutics market	
Country	Million US$ @ retail
European Union	6,000
Rest of Europe	500
Asia	2,300
Japan	2,100
North America	1,500
Total	12,400

Source: Brevoort, P. "The current Medical & Dietary Uses of Botanicals: A market perspective" in July 1996 USP Open Conference on Botanicals for Medical & Dietary Uses: Standards & Information Issues. Proceedings of the Conference. United States Pharmacopeial Convention Inc.

The projected phytomedicine annual growth for 1993-1998 is given in Table 2. Table 3 gives the percentage sales of phytomedicine categories in Europe, 1994.

Table 2: Projected phytomedicine annual growth rate expressed in percentage 1993-1998.

Region	Projected phytomedicine annual growth rate in percentage 1993-98
North America	12++
European Union	8++
Rest of Europe	12
Japan	15
South East Asia	12
India/Pakistan	15

Source: Brevoort P. op. cit.

Table 3: Percentage sales of phytomedicine categories in Europe, 1994

Therapeutic Category	Percentage of Sales
Cardiovascular	27.2
Respiratory	15.3
Digestive	14.4
Tonics	14.4
Hypnotic/sedative	9.3
Topicals	7.4
Other	12.0

Source: Brevoort P. op. cit.

International market prices of top-selling herbs have been published. Some of the more popular herbs such as echinacea and goldenseal sell for quite a high wholesale price of about $30-$50 per pound for their roots. There is at present a shortage of supply of these herbs. The 1996 echinacea crop had been sold before they were harvested. The 1997 crop was being negotiated in 1996. Some may want to try for futures on the 1998 crop. The most expensive herb in the world is wild Chinese ginseng. It sells for $1000 a gram and is traded in the market place.(6)

There is very little published data on retail prices of herbal remedies and how much consumers pay out of pocket for them particularly in developing countries. This information will be essential for health planners and consumer development workers.

Table 1 refers to the phytomedicine market only. As described earlier, herbal remedies could be divided into phytomedicines, nutraceuticals and traditional medicines. The American market for nutraceuticals is about one billion dollars. (7)

A study conducted by the US Food & Drug Administration (FDA) in 1994 showed that, of approximately 1600 respondents to a telephone survey, eight per cent said that within the past year they had used a herbal dietary supplement (Table 4).

Table 4: Prevalence of selected dietary practices in the US, 1994

Supplement use	Percentage not using/using
None	47
Any supplement	53
Vitamin/mineral supplement	42
Amino-acid supplement	06
Herbal supplement	08

Source: Brevoort P. op. cit.

2.A. *Developed Countries*

2.A.i. *Regulation of herbal remedies in the United States*

A 1993 study (8) revealed that Americans were becoming disillusioned with modern health care and were seeking alternatives. About 30 per cent of the adults in the US reported using at least one form of unconventional therapy in 1990 and made about 425 million visits to providers of unconventional therapy contrasting with 388 million visits to modern primary health care physicians.

The same study showed that about three per cent of Americans were using herbal medicines. The consumption of herbal medicines is increasing. A more recent poll of a little more than 1000 adults found that 63 per cent of them said that herbal products would be the answer to many common ailments or part of their daily routine or regime within five years.(9)

Consumer concerns regarding the regulation of herbal remedies in the US has been very well described by Loren D Israelsen.(10) The US FDA has not drafted specific policy statements or regulations to guide industry on safety or approval of herbs, good manufacturing practices or the use of scientific evidence to support proposed claims for herbal products. Over the past several years, the FDA has expressed concerns that herbs are in fact drugs and yet are sold as foods.

Dietary supplements

From a scientific standpoint, the claimed benefits of many of the dietary supplements are better evaluated in pharmacological rather than nutritional terms. Many of the herbal products are being sold as dietary supplements. While some of these consist of herbs traditionally used as food, many are made from plants that have no traditional food use.

Consumers are concerned that herbal products regulated as dietary supplements will not provide an adequate level of safety. Consumers ask for a pre-market safety review for plant derived products marketed as food supplements and compulsory post-marketing surveillance.

Herbal remedies are regulated by two Acts in the US. The more recent one is the Dietary Supplement Health and Education Act of 1994 (DSHEA). This legislation has been the focus of intense debate and consumer concern since the regulation for "health claims" for dietary supplements including herbs under the Nutrition Labelling and Education Act of 1990 (NLEA) became an issue several years ago. How much concern was felt by the consumers can be gauged by the fact that since 1990, the US Congress has received more mail on the regulation of herbal remedies than any other issue including Bosnia, the Gulf war, Somalia, gun control, tax reform and health care reform!(11)

Consumers are very much concerned with the new legal definition of dietary supplements given in DSHEA.(12)

Dietary supplements include:

- a vitamin
- a mineral
- a herbal or other botanical
- an amino acid
- other dietary substance to supplement the diet by increasing total dietary intake
- concentrate, metabolite, constituent extract or
- combination of the above ingredients

Consumers believe that this definition is not any better than no definition since an infinite number of permutations and combinations are possible considering the fact that there are several thousands of herbs and botanicals in the market. This is a pro-industry and anti-people definition of a dietary supplement which has opened the flood-gates!

One provision in the Act prohibits FDA from regulating herbs and dietary supplements as food additives. This brings into focus the FDA concern mentioned earlier namely herbs are drugs but sold as food and the consumer concerns that herbal products regulated as dietary supplements will not provide an adequate level of safety.

The FDA had tried to argue that some dietary ingredients are food additives and therefore require pre-market approval. The industry has opposed this and considers its dietary supplements as foods and therefore regulated as foods. Unfortunately for consumers, several federal courts have agreed with the industry and apparently the Congress agrees.(13)

Consumers view another provision in DSHEA with great concern. A new safety standard has been developed for dietary supplements. A dietary supplement will be deemed unsafe only if it presents a significant or unreasonable risk of injury or illness under the conditions of use on the label. And the burden of proof that a dietary supplement is unsafe rests on the FDA.(14) Consumers cannot understand how FDA can prove a product is unsafe and protect consumers if the agency is not allowed to evaluate the product but must wait until it has evidence that patients are injured by the product. How many consumers have to be injured before FDA can intervene? These are not hypothetical questions as revealed in a news item in the pharmaceutical journal, SCRIP.(15). The US FDA has been taken to courts. Pharmanex, a US marketer of plant based substances recently launched Cholestin as a dietary supplement in compliance with the Federal Food, Drug & Cosmetics Act. The claim on the Cholestin package states, "Maintains Healthy Cholesterol; Reduces Total Cholesterol, Reduces LDL "Bad" Cholesterol, Reduces Triclycerides, and Increases "Good Cholesterol". Pharmanex argues that these health claims fall within the acceptable structure/function claim in accordance with the Nutrition Labelling & Education Act and there is no claim for the treatment of a disease.

Pharmanex is suing FDA to obtain a declaration that Cholestin is a 'dietary supplement' and not a drug. The FDA's Centre for Drug Evaluation & Research wants to regulate Cholestin as a drug based on the labelling claim "reducing cholesterol" and its formulation (it contains HMG CoA reductase inhibitors, including a small quantity of a molecule, identical to that in Merck & Co's lovastin product, Mevacor).

In its law suit Pharmanex maintains that Cholestin should be classified as a natural dietary supplement under DSHEA because it contains food ingredients - Monascus purpureus Went yeast fermented on rice.

Under the DSHEA, as it stands now, FDA has no power to regulate dietary supplements. The agency must prove that patients have been injured by a product before it can intervene.(16)

Consumers will be watching this case with great interest to find out whether DSHEA is going to be pro-industry or whether it can be made to be more consumer-friendly.

Consumers demand legislation that can proactively regulate for safety but never accept an Act that provides for reactive safety regulation after evidence of injury has been proved.

Consumers are very much concerned about the potential dangers of herbal remedies that are being sold as dietary supplements and are often wrongly touted as being free of adverse effects. Since December 1993, dietary supplements containing ephedrine and related compounds have been implicated in approximately 800 reports of adverse effects, including at least eight deaths in the State of Texas alone.(17) That herbal remedies were not necessarily safe simply because they were natural was shown several years ago.(18)

The DSHEA has devised a statutory commission. One of the tasks of this commission is to prepare a report that evaluates how best to provide truthful, scientifically valid and non-misleading information to consumers so that they can make informed and appropriate health care choices for themselves and their families.

Consumers are concerned with the health claims made for dietary supplements. Health claims for dietary supplements - a statement of the relationship of a nutrient to a disease - are regulated by the Nutrition Labelling and Education Act of 1990 which was established in response to a wild proliferation of health claims that was occurring in the 1980s. It was estimated that in the first half of 1990, 40 per cent of new products that were released bore some type of health claim and many of them were not substantiated by science.(19)

But has NLEA helped the consumers to make informed choices by reading the labels on dietary supplements? For example, a structure-function claim for a feverfew product states, "Helps to maintain normal blood vessel tone" and talks about the active ingredient parthenolide which helps to normalise the fraction of platelets in the blood etc.(20) How many consumers can understand this complicated label and make informed and appropriate health care choices for themselves and their families?

It is the elderly who use herbal remedies and dietary supplements most. Studies done at a Senior Health Centre in New Mexico and at the University of New Mexico showed that herbal remedy use is prevalent among the elderly.(21) According to the American Association of Retired Persons Pharmacy Service, from Retired Persons Services, Incorporated (RPS), there has been a tremendous interest among the elderly on the use of natural products as dietary supplements. Consumers have been bombarded with product reports in all types of publications and advertisements, often with conflicting or confusing information. The RPS strongly believes that consumers should not be "guinea-pigs" for unknown product components. Outrageous health claims certainly go too far when they are attached to the following disclaimer. "This statement has not been evaluated by Food and Drugs

Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."(22)

If this is the situation in the US with probably one of the best drug regulatory systems in the world - one that prevented thalidomide from getting registered - what is the plight of developing countries with very weak regulatory systems? This international symposium, will hopefully, provide answers.

Phytomedicines

Several herbal remedies are used by millions of consumers in America for a number of purposes, some of which are therapeutic. The annual market value of phytomedicines in 1994 was $1.5 billion. However there is no special Act under which phytomedicines can be registered. Herbal remedies, for minor self-limiting conditions, are registered under the OTC drug review process that began in 1972.

Many industrialised nations have developed regulatory models that provide for safety approval and proof of efficacy for many of their herbal products either based on:

- Evidence of traditional use; or
- Modern scientific information.

In 1991 a group of leading US and European phytomedicine companies formed the European American Phytomedicine Coalition (EAPC) and petitioned the US FDA for European marketing histories for botanical ingredients to be eligible for inclusion in the OTC drug review process that began in 1972.(23)

The European regulatory models accept histories of traditional use of herbal remedies as evidence of safety. These are called old drugs and are subject to a more lenient approval process. **There is, thus, an enormous legal difference between new and old drugs in Europe. This is not the case in the US.**

European phytomedicine companies have been unable to sell in US as drugs, herbal remedies regulated as medicines in their countries. It was to overcome this barrier that EAPC had petitioned the US FDA to accept European marketing approval. Upto 1996, the FDA has not responded.

The constraints to registering herbal remedies as OTC drugs and the limitations placed on health claims for dietary supplements, have led many to suggest that the US should develop appropriate legislation to review and approve herbal remedies as legitimate OTC drugs. **The American Herbal Council, the Herb Research Foundation and the Americal Herbal Products Association support a separate traditional medicines category in addition to dietary supplements in order to arrive at a more rational framework for the regulation of herbal remedies (24, 25).**

American consumers' concerns are not limited to the safety, efficacy and quality of herbal remedies. Equally distressing is the communication and information vacuum that surrounds herbal remedies. Seven out of 10 consumers who use

herbal remedies do not tell their primary care physicians that they are taking them; presumably they do not tell their pharmacists either.(26) Critical information essential for prescribers and dispensers to be forewarned about possible drug interactions are withheld.

Consumers may not be telling their physicians either because the latter do not ask them or because consumers are under the mistaken belief that herbal products are not medicinal products but dietary supplements.

Consumers do ask their pharmacists. In fact, 74 per cent of pharmacists are asked about herbal remedies. This was revealed in a recent survey by Texas Pharmaceutical Association. Often their answer was very simple - "I do not know!"(27)

From a consumer point of view the pharmacist's role in providing objective information is vital. They stock herbal products and are expected to make appropriate product selection for consumers. Pharmacists therefore need to be adequately knowledgeable on the safety, efficacy and quality of herbal products. They also have to provide information to other health care professionals. At present there are no authoritative sources from where pharmacists can obtain the relevant information. Consumers look forward to this symposium to find appropriate solutions to this concern of consumers.

2.A.ii. *The United Kingdom*

As in the US, many people in the UK use herbal remedies for minor self-limiting conditions. The failure of modern medicine to cure and anxiety about their potentially serious unwanted effects have led some to turn to herbal remedies for the treatment of more chronic and disabling conditions as well often in the (mistaken) belief that time-honoured natural medicines must be safe.(28)

The Medicines Act of 1968 initially exempted herbal remedies from licensing requirements and did not restrict their supply. Subsequent legislation recognised that certain plants and herbs had powerful pharmacological effects and restricted their sale and supply to pharmacies while still permitting prescribing herbalists to use some of them within specific dosages.(29)

In the 1980s about 5,500 herbal products were available either as pharmacy medicines or on the general sales list. Of these about 1000 products derived from 550 herbs were estimated to be on the market with product licences of right. The Committee on the Review of Medicine (CRM) were examining them. Assessment of their safety, efficacy and quality was difficult. Few herbal remedies have been evaluated by clinical trials. CRM had decided to accept bibliographic evidence of efficacy even where this is only an appropriate reference in a herbal pharmacopoeia.(30)

Medical herbalists choose and prepare medicines and accept responsibility for their recommendations. Herbalists can practise without a formal qualification but a few are also medically qualified.(31) However, relatively few people consult a medical

herbalist. Some go to pharmacies but health food shops and department stores are the main sources from which consumers buy their herbal remedies often selecting them with no qualified advice.(32) Supply of herbal remedies by mail order is also increasing and this accentuates the problems of unsupervised self-medication.

2.A.iii. *Germany*

The Commission E of Germany, which is considered to be the leader of the industrialised nations in evaluating herbs, employs criteria that include long term, traditional and historical use. However, documentation by some type of modern scientific data - chemical, toxicological, pharmacological, clinical, epidemiological or case history - is required to confirm the safety and efficacy of the long-term use of herbs. The Germans have what has been called a "doctrine of reasonable certainty" which is the criterion they use for determining the efficacy of a herb, but they go by a "doctrine of absolute certainty" with respect to safety. So while safety is not a negotiable issue, efficacy is reviewed using a more relaxed standard.(33)

Herbal remedies, called phytopharmaka, are registered under the medicines Act-Arzneimittelgesetzs - and are allowed to make health claims and indications for use on the labels. There are in addition, other herbal products, not registered as drugs; they cannot make any health claims.

The total number of registered medicinal drugs in Germany is about 50,490. Of these about 6080 or 12 per cent are herbal phytopharmaka. Majority are OTC products; some can be dispensed by prescription only. In addition to phytopharmaka, there are about 6900 registered homeopathic drugs which may include herbal ingredients. These are also allowed to make health claims and state indications for use on the labels. Yet another group of drugs are a combination of modern chemical substances and herbal ingredients. In addition to these herbal remedies which are registered as drugs, there are herbal products which do not make any health claims and are used as foods and drinks. These are not controlled by the Medicines Act. Practitioners of modern medicine prescribe herbal medicines which are paid for by the social health insurance. However, they do not have any specialised training in prescribing phytopharmaka. A recent review showed that in 1970, 52 per cent of all Germans used phytopharmaka; a survey done in 1997 revealed that 70 per cent use phytopharmaka now.(34)

Table 5 gives the pattern of utilisation of modern and traditional herbal drugs in Germany, for three commonly used therapeutic categories of drugs in 1995. Defined daily doses (DDD) of the modern and traditional medicines of each therapeutic category are given.

Table 5: Patterns of Utilisation expressed in DDD of modern and traditional herbal remedies of three commonly used therapeutic classes of drugs in Germany in 1995

Therapeutic category	DDD in millions 1995	Percentage change in 1995 over DDD in 1994	Cost in Marks per DDD	Total cost in Marks (Millions)
Modern psychotropics	966.3	+ 2.5	1.5	1413.8
Herbal psychotropics	167.9	+33.0	1.0	167.9
Modern cardiac glycosides	676.8	- 5.3	0.23	157.7
Herbal cardiac glycosides	192.8	+ 6.8	0.67	129.0
Modern immune therapy drugs: liposaccharides & oligosaccharides of bacterial origin Homeopathic immune therapy drugs: mostly herbal	12.0))) 38.0)	+ 5.5	1.29	64.4
Herbal immune therapy drugs	58.2	+28	1.44	83.8

Source: Monika Scheffler, BukoPharma Kampagne, Bielefeld, Germany, Ref. 33.

Psychotropics and cardiac glycocides are essential, prescription only drugs; cardiac glycocides are life-saving drugs; an advanced industrial country and the home of one of the biggest multinational drug company, Hoechst, is going back to traditional medicines for treating major and life-threatening illnesses. The annual increase in the utilisation of herbal psychotropics was 33 per cent compared to three per cent for modern psychotropics. Herbal cardiac glycocides are three times more expensive than modern cardiac glycocides. Yet the utilisation of herbal glycocides has increased while that of modern glycocides has decreased. It is relevant to note that ACE inhibitors are being increasingly used in the management of heart failure. Inspite of this, the use of herbal cardiac glycosides has increased.

Immune therapy drugs are non-essential. Their efficacy has not been proved. Preparations of liposaccharides and oligosaccharides of bacterial origin - brand names Broncho-Vaxom, Symbioflor I and Luivac - constitute the 12 per cent "modern" drugs.'

A single plant medicine marketed to increase cerebral circulation achieved a turnover of 120 million pounds (about DM280 million) in 1989. Germany has been described as the Garden of Eden for herbal remedies.(35)

2.A.iv. *Japan*

Traditional medicines in Japan are based on traditional Chinese medicines introduced into Japan more than a 1000 years ago. The Pharmaceutical Affairs Division of the Ministry of Health & Welfare issued new regulations in 1985 setting quality control standards for ready to use traditional drugs. Traditional drugs of standard quality became available on the market a year later. They are used by more than 40 per cent of the physicians in their routine practice.(36) More than 100 kinds of traditional medicines (Kampo drugs) have been placed in the national health insurance scheme. The government is increasingly recognising traditional medicine. There has been multisectoral research on herbal medicine and acupuncture funded by the Japan Science and Technology Agency.(37)

Quality assurance requires specifications and test methods employed in the major phases of production: raw materials, the extract, and the final dosage form, e.g. tablet, capsule, granules, etc. In assessing the safety and efficacy of traditional medicines, two broad approaches are used. For medicines that have been used over a long time in Japan, safety and efficacy are accepted because of the long history of uneventful use. Therefore for this category, no data demonstrating safety and efficacy need be submitted. On the other hand, other products that have been recently introduced, e.g. new formulations, should be treated as any new pharmaceutical product. For these, data are required to demonstrate safety and efficacy, including data on clinical trials. The Good Manufacturing Practices (GMP) for traditional medicines were developed voluntarily by the Japan Chinese - Medicine Manufacturers Association. It is known as "Regulations for Manufacturing Control & Quality Control of Ethical Extract Products in Kampomedicine (Oriental Medicine) Formulations.(38)

2.A.v. *Australia* (39)

Prior to 1991, there were no Commonwealth Controls exercised over herbal products which were, at that time, often treated as foods. In 1989 a new Therapeutic Goods Act (TGA) was passed by parliament (replacing the old 1966 Act).

Requirements for herbal medicines

Herbal products are recognised as medicines where they meet the definition of a 'therapeutic good'. This includes:

- Anything used for the prevention, treatment or diagnosis of diseases and other bodily conditions in humans or animals; and
- **Any product that is likely to be thought to be a therapeutic good for any reason, most often because of the advertising, dosage form or appearance (emphasis mine).**

All medicines supplied in or exported from Australia must:
- first be approved by the TGA
- be made by a manufacturer with an acceptable standard of good manufacturing practice (GMP)
- comply with relevant standards, for example: labels, advertising, raw material

standards, finished product liability, tablet disintegration.

All products are assessed for basic safety and quality. Further evaluation to consider the safety in more detail and efficacy of the product is required if there could be some risk to the consumer.

Herbal and traditional medicines are evaluated by the Traditional Medicines Evaluation Committee (TMEC). Where herbal medicines are eaten or made into teas only for nutrition or flavour, these would be considered to be foods, not medicines. Where herbal products are made solely to moisturise or cleanse the skin, these would be considered to be cosmetics, not medicines.

Medicines made by herbalists (and other practitioners) for individual patients following a consultation are exempted from controls in the Act, but these medicines should meet acceptable standards. The standard of professional practice by herbalists (and other practitioners) is controlled by States & Territories.

Medicines in Australia fall into one of the following three groups:

- Registrable medicines;
- Listable medicines; and
- Exempt medicines

Registrable medicines

Prescription drugs, OTC drugs and other medicines where safety and efficacy need to be considered must pass through the "Registration" process before approval. In addition, the standard of the manufacturer must be acceptable. Where a product is approved for Registration, a *Certification of Registration* is issued.

In the case of herbal medicines, full evaluation (Registration) is required if:

- the product contains a substance that is a scheduled poison, e.g. certain toxic herbs;
- the product contains an active ingredient from an animal or mineral source where this ingredient is not permitted in the "Listed" products;
- the product is to be used for a serious condition which should be monitored by a practitioner or the product needs to be sterile e.g. eye drops and injections.

TMEC will, at its discretion, accept evidence of established traditional use as proof of efficacy. Where there has been a long period of safe use, only limited toxicological data is required.

Listable medicines

Low risk medicines - mostly herbal medicines, vitamin and mineral products, sunscreens and some homeopathic products - go through the "Listing" process before approval. These products are assessed for quality and safety. To ensure safety, only certain ingredients are allowed in these products. For some ingredients, only a safe

dose or a particular route of administration is allowed. The standard of the manufacturer must be established as acceptable.

Proof of efficacy is not usually requested, although the product sponsor is required to hold this information as a condition of Listing. Where a product is approved for "Listing", a *Certificate of Listing* is issued. Information about registrable and listable medicines is stored in the Australian Register of Therapeutic Goods (ARTG) database.

There are over 1, 500 different herb species in the medicines being supplied in Australia. Most herbs are permitted to be included in "Listed" products. It is estimated that two-thirds of "Listed" products in the Australian Market contain one or more herbal ingredients. There are approximately 400 "Listed" products imported from China.

About 27,000 Registered and Listed medicines are supplied in Australia. A quarter of them are manufactured overseas.

ARTG - Exempt medicines

Minimal risk medicines do not need to be evaluated or assessed prior to marketing. Suppliers of raw materials do not need to apply for approval to sell the material to practitioners and other manufacturers who use the material to make a finished product. Medicines made by herbalists (and other alternative medicine practitioners) for individual patients following a consultation do not need a TGA approval before being sold to the patient. Most homeopathics are exempt. Details of raw materials, practitioner dispensed products and most homeopathic products are not stored in the Australian Register of Therapeutic Goods.

Advertising to the public

In most cases, medicines cannot be advertised to the public for serious conditions that require supervision by a trained practitioner. The *Therapeutic Goods Advertising Code* sets out conditions that may not be mentioned in advertisements to the public.

These restrictions do not apply to communication between a practitioner and patient and also do not apply to information in books and journals.

Hundreds of tonnes of illegal herbal products are seized each year in Australia. But compared with the total trade in herbal medicines, the authorities are confident that high standards are maintained in Australia.

2.A.vi. *Adverse reactions to herbal remedies reported in developed countries*

There is a long list of medicinal plants that are toxic to the liver.(40-43) Germander has been used with apparent safety for centuries. It was in the early 1990s, that germander was first identified as a hepatotoxic drug.(44) In May 1992, all preparations containing germander were withdrawn from the market and banned in

France. This lead was not followed in Canada, where the first two cases of hepatitis were reported recently.(45)

Four cases of acute hepatitis attributable to single plants or mixtures were reported in British patients taking vallerian and scutellaria.(46) Valerian is one of the top selling herbs in the US.(47)

In Belgium 70 cases of renal impairment attributable to preparations based on Chinese plants were recently reported.(48)

A neonatal death where a mother had been drinking herbal tea was reported in 1988.(49) The mother had regularly taken an infusion based on 10 different plants during the pregnancy. A causal link with herbal tea is difficult to establish but this calls for caution during pregnancy.

One research field that has been neglected and poorly studied is the potential interaction between herbal remedies and modern pharmaceuticals.(50) This is another consumer concern since many people both in developed and developing countries take herbal remedies and modern drugs together and do not reveal this to their physicians or pharmacists.

2.B. *Developing Countries*

Traditional systems of health care and herbal remedies were freely available in developing countries for several centuries. The WHO came into existence in 1948 as the international agency mandated to ensure a healthy world. Several programmes were initiated. However, it was in 1976 that WHO decided that traditional healers and midwives, previously seen as an obstacle to progress, must play their part.(51) The Traditional Medicines Programme under a Director was set up in 1978. Consumers were told, among other things that:

- The goal of Health for All by the Year 2000 cannot be achieved without traditional medicine;
- Without traditional medicine most Third World people would have no medicines at all;
- Traditional systems of health care provide primary health care to about 80 per cent of the population who have no regular access to modern health care services.

These statements bring into focus a major consumer concern. What is WHO's policy on traditional medicine? Does the WHO consider traditional medicine as merely a substitute for modern medicine when the latter is either not accessible, available or affordable to the poor in the Third World? Or is traditional medicine a valid health technology in itself?

In the mid seventies, it was estimated by the WHO, that about 80 per cent of the world's people had no access to modern health care. As recently as 1993, it was reported by the Director of the WHO Traditional Medicine Programme that 80 per

cent of the world's inhabitants rely chiefly on traditional medicines, mainly plant based, for their primary health care needs.(52) It is difficult to understand how this precise numerical value was arrived at and the particular research methodology used to determine it. However it must be taken as authoritative since it was given by the Director of WHO Traditional Medicine Programme. It is relevant to note that this figure fits very well with the other side of the coin. More than 80 per cent of health budgets in developing countries are directed to services that reach approximately 20 per cent of the population.(53) This figure refers to modern health services. **It would therefore appear that whether in the seventies, eighties or nineties, according to the WHO, 80 per cent of the world population depended on traditional medicine because modern health care was not accessible, available or affordable to them. Consumers want an explanation why there was no improvement inspite of the enormous resources WHO had put into its several programmes. But this Symposium is not the forum to bring up this issue.**

2.B.i. *WHO, developing countries and traditional medicines*

In 1978 the Traditional Medicine Programme was set up. A WHO Report (54) proposed that traditional medicine should be integrated with primary health care. This integration, the report stated, "offered the best means of achieving the goal of Health for All by the Year 2000". In September 1987, the Regional Director of the Western Pacific Region stated that while the WHO programme on traditional medicine made considerable progress in acupuncture, not much has been achieved in herbal medicine.(55) In November 1987 the Director-General of WHO deplored the fact that recognition of traditional medicine in the Member States was still low. He added that the safety and efficacy of traditional medicine have not been fully validated; its rational use had still to be defined.(56)

In 1993 the second evaluation of the implementation of the global strategy for Health for All by the Year 2000 was published for the South East Asian Region. In this report there was a brief mention of traditional medicine in only two countries, Mongolia and Myanmar, out of a total of 11 countries in the region.(57) In 1995, the WHO Report "Bridging the gap" was published. The report had 118 pages. But only a small fraction of one page out of the 118 pages was devoted to the topic of traditional medicine. However, the report stated that traditional medicine continued to be an important part of health care in many developing countries; but admitted that traditional medicine had not been integrated into most national health care systems.

What the WHO had failed to do in the Member States - inability to integrate traditional medicine with the modern health care systems - it has succeeded in its headquarters in Geneva. The Traditional Medicine Programme has been integrated with the Essential Drugs Programme. The post of Director, Traditional Medicine has been reduced to that of Medical Officer who works in the Essential Drugs Programme. The current budget for traditional medicine is in the region of $180,000 per annum. This sum includes the salaries of the medical officer and the secretary, travel and grants for traditional medicine activities.(58)

This scaling down of the Traditional Medicine Programme is a cause for serious consumer concern as it means that the recognition of traditional medicine as a health technology which needs to be promoted and strengthened in developing countries is given a low priority by WHO. This is all the more disturbing since the Director General of WHO had stated that the safety and efficacy of traditional medicine have not yet been fully validated. Providing technical assistance to developing countries so that they can ensure the safety and efficacy of herbal remedies which consumers use is the sole responsibility of the WHO.

Consumers, therefore, look to UNIDO and this symposium with great expectations.

2.B.ii. *Consumers' perception of traditional medicine*

While there is a fair amount of published evidence that consumers in developed countries are turning more towards using traditional medicine, there are no recent reports that have studied consumer perception of traditional medicine in developing countries.

Prof. D. Banerji, formerly of the Jawaharlal Nehru University of New Delhi, in one of his early studies in the 1950s, reported on the perceptions of traditional medicine in the rural population in North India. One of the items in the questionnaire he used was, **"If you have enough money and easy access to both the traditional and modern systems of medicine, which one will you choose?" The vast majority of the respondents opted in favour of the modern system.(59)**

Both modern and traditional medicine are equally accessible and available in China. A study reported in 1978 described the incorporation of traditional medical practice into the organised health care system taking as an example the health care services in Toushan, a community with a total population of 57,934.(60)

It was left to the people in Toushan to choose between modern and traditional systems both of which were freely available. In 1977 the ratio was 7:3 in favour of the modern system.

It was also estimated that nearly 70 per cent of the medicinal materials consumed by the commune health clinic were modern pharmaceuticals.

It appears that people in China and India prefer modern medicine to traditional medicines. Very rough estimates for the utilisation of traditional medicines in the Asia Pacific region vary from about 35 per cent in Sri Lanka to over 75 per cent in Nepal. However, it is important to remember that there is no exclusive use of traditional medicine by one section of the population and modern medicine by another. **A vast majority of consumers in developing countries use both, modern and traditional medicine; they may also take them simultaneously but do not tell this to their physicians.**

They may be self-medicating with an OTC herbal remedy, a herbal dietary supplement or taking traditional medicine prescribed by a traditional healer. As in the developed countries, there is a perception in developing countries that, because they are "natural" and have been used with apparent safety for several centuries, herbal remedies are always safe.

2.B.iii. *Malaysia and Pakistan*

Regulatory systems for the control of traditional medicine vary widely among developing countries. Malaysia, for example, introduced the Drugs & Cosmetic Control Act (1984) to regulate and control traditional medicine.(61) Only those preparations that are processed and presented in modern dosage forms such as tablets, capsules and oral liquids will be subjected to evaluation, approval and registration. Raw materials such as seeds, or any parts of plants will not be registered.(62) These will include herbs sold as food or drinks such as herbal teas which are not regulated. For example, the advertisement for "Tea of Longevity" states, "suitable and beneficial to many ailments including migraine, weak heart, hernia, menstrual pain, kidney stones, rheumatism, arthritis, sexual stress, impotence, frostbite, internal and external cancer and infections". A retail pack of 150 mg costs between 160-240 Malaysian Ringgits (US$62-96).(63) This is equivalent to 10 days wages of an unskilled worker in Malaysia.

The mandatory registration of traditional medicines is not intended to give recognition to traditional healers, who are not recognised in Malaysia.(64)

Consumers' safety in Malaysia, therefore depends on the control of traditional medicines in the market through a system of evaluation, approval and registration. Traditional healers are not recognised and are not held responsible for the safety of the medicines they prescribe and dispense.

A problem faced by the drug regulatory authority in Malaysia is the enormous work involved. Several thousands of traditional medicines have been submitted for approval. It will not be possible with the available resources to evaluate all of them for safety and quality and to continue to monitor them in the market.(65)

The annual market for traditional medicines in Malaysia is approximately US$800.(66) This is more than double that of the market for modern pharmaceuticals which is about US$350.(67)

In Pakistan, on the other hand, all traditional healers are registered by the Ministry of Health. They are responsible for the safety, efficacy and quality of the medicines they prescribe and dispense. There is no regulatory control of traditional medicines.(68) Not all the traditional medicines consumers use are purchased from the traditional healers. **Regulating the traditional healers and not the traditional medicines will therefore, not ensure consumer safety.**

2.B.iv. *Vietnam*

The use of traditional medicines in Vietnam is regulated and controlled in two distinct ways.(69):

i. The use of compounded herbal remedies is controlled primarily by mandatory registration of practitioners. Each traditional practitioner needs permission from the Provincial Health Service to dispense and sell herbal remedies and they are responsible for the safety and quality of the products they prescribe.

ii. A small number of herbal remedies of proven safety and efficacy are permitted to be manufactured on an industrial scale. All manufactured products must be registered by the Ministry of Health. Provisional registration is accorded in the first instance and remains valid for one year.

In 1976, the Ministry of Health promulgated a pharmacopoeia which included monographs on medicinal plants. A formulary which promotes the rational use of essential drugs for primary health care and in which both modern essential drugs and medicinal plants are mentioned, has been compiled and published with WHO support.

A national workshop in November 1986 reported on the successful application of traditional medicine in the fields of internal medicine, surgery, gynaecology and ophthalmology.(70) Vietnam is perhaps the only country where modern and traditional medicine, merged in medical education, are jointly practiced within a single health service.(71)

2.B.v. *Thailand*

The Ministry of Health promotes the use of 66 traditional medicinal plants in primary health care (PHC). This is based on the scientific evidence of efficacy of these plants as well as on traditional patterns of utilisation. The Ministry of Health also promotes the use of traditional medicine in state-run hospitals and health service centres. The Fourth Public Health Development Plan (1977-81) stated the country's general policy to promote the use of traditionally used medicinal plants in PHC. The Seventh Plan (1992-1996) promotes the integration of traditional Thai medicine into community health care and gives priority to research into medicinal plants.(72)

The most effective use of traditional herbal medicines in PHC in Thailand is their role in self-medication. Most Thais in rural areas treat themselves first before seeking help from either modern or traditional medical practitioners; herbal medicines offer a low cost intervention in the early treatment of disease. **What is important to recognise is that this practice of self-medication with herbs provides a much safer alternative to the serious problem of self-medication with inappropriate doses and various combinations of harmful drugs which are freely available.(73)**

Table 6 gives the pattern of health care service utilisation in Thailand in 1970, 1979 and 1985.

There is a definite shift away from traditional practitioners to modern health facilities inspite of the government's policy of promoting the use of traditionally-utilised medicinal plants.

There is also a fall in the percentage of the population resorting to self-medication.

Table 6: Pattern of utilisation of health care services in Thailand, 1970, 1979 and 1985 expressed in percentage.

Source of Health Care	Percentages		
	1970	1979	1985
Take no medicine	2.7	4.2	6.3
Traditional practitioners	7.7	6.2	2.4
Self-treatment and self-medication (medicines bought at drugstores)	51.4	42.4	24.4
Government health centres	4.4	16.8	13.3
Govemment hospitals	11.1	10.0	32.8
Private clinics and hospitals	22.7	20.4	20.8

Source: Ministry of Public Health (1978: 45 and 1982: 78) United Nations (1986) Institute for Population and Social Research (1987) quoted in The Triumph of Practicality. Ed. Stella R. Quah Published by Institute of South East Asian Studies, Singapore, 1989.

Whether consumers use traditional or modern medicines to self-medicate is not known. However, herbs are available in the market in various forms of commercial products, including cosmetic lotions, creams and soaps as well as a vast pharmacopoeia of herbal preparations in modern dosage forms. Food and dietary supplements with medicinal properties are also available. About 100,000 traditional healers were involved in the preparation of herbal medicines in 1987 but few of them were practising healing full time.(74)

2.B.vi. *Republic of Korea*

The Republic of Korea is unique in that traditional medicine is favoured equally by all levels of society. Health insurance coverage is available for traditional medicine and traditional medical practitioners typically earn more than modern medical practitioners due to the popularity of the traditional approach to health care. However, only 15 to 20 per cent of the national health budget is allocated for traditional medical service.(75)

The traditional medicine market is estimated at about $2 billion a year or per capita consumption of $46 per year. Pharmacists trained in Western medicine wanted to

enter the traditional market. The Government held an examination to license these pharmacists to practice traditional medicine. The traditional healers demanded that the examination be declared null and void alleging that the examination was too easy and threatened to close all their shops if their demands were not met.(76)

It would appear that the Republic of Korea is perhaps the only country where a pharmacist has to be licensed in traditional medicine before he can stock and sell traditional medicine. The per capita consumption of modern pharmaceuticals is 33.9.(77) This is lower than that of the per capita consumption of traditional medicine.

2.B.vii. *India* (78)

Traditional medicine in India is regulated by the Drugs & Cosmetic Act 1940 (Act No. 23 of 1940). This Act regulates the import, manufacture, distribution and sale of drugs. A separate section deals with traditional drugs. There are three well known and widely used systems of medicine in India, namely Ayurvedic, Unani -Tibb & Siddha. Each system uses its own variety of herbal remedies. For the purpose of this Act, all herbal remedies belonging to these three systems are collectively known as Ayurvedic drugs.

Drugs & Cosmetics (Amendment) Act 1982 defines Ayurvedic drugs as follows:

> "Ayurvedic drugs include all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals and manufactured exclusively in accordance with the formulae described in the authoritative texts of Ayurvedic, Unani-Tibb & Siddha systems of medicine specified in the First Schedule".

There are 54 Ayurvedic texts mentioned in the first schedule. Administratively, the traditional and modern systems are separate. There is a central or federal department for the Indian System of Medicine (ISM) at the Centre in New Delhi, and each state has a directorate for ISM.

A recent Amendment to Section J of Drugs & Cosmetics Act has triggered a debate between a section of the national Ayurvedic industry and consumers.

Under an amendment introduced in January 1996, drugs for liver disorders, memory enhancement and several other ailments for which Ayurvedic remedies exist, can no longer be advertised as cures for these disorders.

A spokesperson for a national Ayurvedic drug company described the amendment as the deathknell for the Indian herbal drug industry which may be wiped out by the year 2005. On the other hand, the Indian Council for Medical Research (ICMR) and consumer organisations have welcomed the amendment, saying that some sort of regulation is necessary to ensure the safety, efficacy, quality and manufacturing practices of medicines sold over-the-counter as Ayurvedic drugs.

However, this amendment does not prevent medical representatives from recommending their products to physicians. This, say spokepersons for the small scale industry, will be discriminatory. The larger companies will recruit an army of medical representatives to promote their products to physicians in their clinics. Small firms will not be able to do this.(79)

Research & Development

Research & Development (R & D) on indigenous medicinal plants have been going on since Col. Chopra initiated R & D in the School of Tropical Medicine, Calcutta about 50 years ago.

Several research institutes and university departments are actively engaged in R & D on the Indian systems of medicine. Many of these have been funded by the Indian Council for Medical Research. The Central Drug Research Institute (CDRI), Lucknow was established in the late fifties.

CDRI and other research institutes are focussing their R & D efforts to isolate new active ingredients from medicinal plants to develop new drugs and obtain patents on them.

Consumers are disappointed that these research institutes have not addressed consumers' concerns about the safety, efficacy, quality, costs and manufacturing standards of the tens of thousands of Ayurvedic drugs and particularly those that are skillfully and aggressively promoted. Consumers pay enormous amounts to purchase them.

A good example is the German Ayurvedic drug Essentiale. Messrs Rhone-Poulenc markets this drug as a "Membrane-therapeutic agent for liver diseases" and sold 943,140 units valued at 41.1 million rupees in 1994.

It was left to a consumer organisation, the Foundation for Health Action, Calcutta, to get the manufacturing licences for this drug, given by FDA in the States of Maharashtra and Gujerat, cancelled effective on 25-6-95 and 15-3-96 respectively on the grounds that there was no evidence of its efficacy and that it was not an Ayurvedic drug according to the Drugs & Cosmetic Act.(80, 81)

However, this drug is imported and available in the market in India and is prescribed exclusively by practitioners of modern medicine.

Multinationals and traditional medicines

The Drugs and Cosmetics Act does not recognise herbal remedies; it only recognises Ayurvedic drugs manufactured in accordance with 54 ancient texts. Notwithstanding this a few multinational companies have changed their manufacturing licences for well known allopathic OTCs to Ayurvedic drugs. For example, Smith Kline Beecham now markets Iodex as an Ayurvedic drug. Proctor & Gamble markets Vicks Herbal. It is relevant to note that traditional drugs have no excise duty. **In order to legitimise**

their claim that these are traditional medicines the manufacturers have substituted the chemical names of the ingredients with Sanskrit or older English names. For example, the camphor in Vicks Herbal is Karpoora; citric acid in Eno's fruit salt is Nimbasaar; methyl salicylate in Iodex is Oil of Wintergreen.

In India practitioners trained in modern medicine though not trained in other systems or medicines can freely prescribe medicines belonging to other systems. Examples are the Ayurvedic drugs such as Essentiale, Ginsec (Dupher Interfran), and Liv 52 (Himalaya Drug Company).

However practitioners trained in other systems cannot prescribe modern medicines. In July 1992 a homeopathic practitioner treated a patient with paracetamol and an antibiotic. The patient later died of complications of typhoid fever. The homeopath was taken to court and the Supreme Court found him guilty of *negligence perse*, because the Indian Medical Act prohibits any person without the requisite qualification in allopathic system of medicine to practice in that system. The judges further stated:

"A person who does not have knowledge of a particular system of medicine, but practices in that system is a quack and a mere pretender to medical knowledge or skill or to put it differently a charlatan."(82)

Based on this judgement, can practitioners of modern medicine who prescribe Ayurvedic drugs be called quacks or charlatans? Consumers are concerned that there is uncontrolled cross-practice - practitioners not trained in a particular system using drugs belonging to that system indiscriminately.

3. Evaluation of traditional medicines

Clinical pharmacologists and other scientists working on medicinal plants focus all their attention on isolating and identifying biologically active ingredients in medicinal plants and herbs.

Traditional pharmacologists argue that the efficacy of herbal remedies is due to the synergistic activity among the several ingredients of herbal mixtures. Complex mixtures of plants or herbs form the basis of traditional medicines. The mixtures are usually subject to crushing, heating, boiling, etc. It is possible that this process may change the chemical structure of the active ingredient in the plants.

Traditional healers do not accept that the efficacy is necessarily due to the active ingredients in the plant. According to them, modern clinical pharmacologists by their "active ingredient" approach, take the knowledge from the plant but throw away the wisdom of centuries.

If there is acceptable historical evidence that traditional herbal remedies have been effective in the treatment of certain diseases, but neither their active ingredients nor the mechanisms are known, will it be ethical or moral not to

accept and use that treatment? Some examples of successful treatment by traditional medicines will be useful to answer these questions.

In the late 1980s children attending the Dermatology Department, Hospital for Sick Children, Great Ormond Street, London showed marked improvements in their eczema symptoms. These improvements were due to oral treatment with aqueous decoctions of a mixture of 10 Chinese medicinal herbs.(83) Clinical experimentation and pharmacological testing revealed that a mixture of the 10 herbs were necessary and that the efficacy could not be attributed to any single active ingredient from any one of the 10 Chinese herbs. A placebo controlled double-blind clinical trial using the 10 Chinese herbs was carried out on 47 selected children with non-exudative eczema.(84) The conclusions of the trial were to validate to the standard of current conventional clinical trials utilised in the UK that the traditional Chinese therapy was efficacious.

If these children had to wait till the clinical pharmacologists had screened the 10 Chinese plants for active ingredients and tested them for biological activity, they would never have been given the chance of getting effective treatment with a mixture of 10 Chinese herbs.

Potential cytotoxic drugs are tested for their activity against experimental or human cancer cells. Efficacy depends on the ability to kill specific cancer cell types without affecting normal body cells. Studies on the effects of certain Ayurvedic herbal preparations for possible cytotoxic activity revealed that these herbal preparations did not kill the cancer cells but transformed them into normal healthy cells.(85) These drugs, therefore, have a different mechanism of action. Classical testing methods would have missed this important anti-cancer activity.

I wish to conclude this section with a philosophical question. Is medical science one universal and uniquely expressed (western) paradigm - a biomedical paradigm? If it is possible to conceive of alternative methodologies, theories and practices in other domains such as music, logic, linguistics, art and politics, is it not possible to consider possibilities of alternative methodologies in medical science, knowing that doctors practice medicine within a biopsychosocial paradigm?

The guiding principles by which knowledge is built up in the biomedical paradigm are those of the scientific method where hypotheses are clearly stated, then tested and accepted or rejected as truth "until further notice" or "within the stated confidence limits" using only experimental or quasi-experimental designs - a deductive approach to problem solving.

Is it possible for research scientists to examine other methodologies, for example, using experiential methods - an inductive approach, to evaluate traditional herbal remedies?

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Consumers International
Regional Office for Asia and the Pacific
PO Box 1045, 10830 Penang, Malaysia
Tel: (60-4) 229 1396; Fax: (60-4) 228 6506
Email: ciroap@pc.jaring.my
Website: http://www.consumersinternational.org